K050033

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MEViSYS

(주)메비시스

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
Oct 25, 2004

Submitter's Information: 21 CFR 807.92(a)(1)
Mevisys, Co., Ltd.
Alumni Venture Hall, Room 5103
KAIST,
400 Gusongdong Yusonggu
Daejon 305-701
Korea

Trade Name, Common Name and Classification: 21 CFR 807.92(a) (2)

Trade Name:	Lucion™
Common Name:	Picture Archiving Communications System
Device Classification Name:	892.2050
	System, Image Processing

Predicate Device 1: 21 CFR 807. 92(a) (3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K022692
Device Name	VOXELPLUS PACS
Applicant	Mevisys Co.,Ltd. KAIST-AVH 5103, 375-1 Guseong-dong Yuseong-gu Daejeon 305-701, Korea
Contact	Carl Alletto
Product Code	LLZ
Date Received	08/13/2002
Decision Date	10/11/2002

Predicate Device 2:

Device Classification Name	SYSTEM, X-Ray, Tomography Computed
Regulation Number	892.1750
510(k) Number	K020929
Device Name	SmartScore 3.5, 4.0, 4.5

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Applicant	GE Medical Systems. 283 Rue De LaMiniere Bp34, Buc Cedex, FR 78533
Contact	Carl Alletto
Product Code	JAK
Date Received	03/22/2002
Decision Date	04/03/2002

Device Description: 21 CFR 807 92(a) (4)

Mevisys Lucion™ is a PC-based software application that imports medical images (i.e. CT, MRI modalities) in a DICOM format and provides various functions for rapid and easy review. It includes 3D volume rendering, various MPR, and many 2D analysis tools. The tools manage images, requests, patients, examination etc. over a high-speed network to allow information and images flow throughout a user facility.

Indications for Use: 21 CFR 807 92(a) (5)

The Lucion™ is a software application for the display and 3D visualization of medical image data derived from various sources (i.e. CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a) (6)

The device is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b) (1)

The 510(k) Pre-Market Notification for Lucion™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. Lucion™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Mevisys Co., Ltd.
% Mr. Richard C. Lanzillotto
US Agent
North American Technical Services Corp.
30 Northport Road
SOUND BEACH NY 11789-1734

Re: K050033
Trade/Device Name: Lucion™ Picture Archiving and Communications System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 5, 2005
Received: January 11, 2005

Dear Mr. Lanizillotto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MEViSYS
(주)메비시스

(Indications for Use Form)

510(k) Number: K050033

Device Name:
Lucion™ by MEViSYS Co. Ltd.

Indications for Use:

The Lucion™ is a software application for the display and 3D visualization of medical image data derived from various sources (i.e. CT scanners, MRI scanners). Images and data can be acquired, stored, communicated, processed, printed, rendered, and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050033